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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,246	07/24/2003	Christopher J. Elliott	10123/00601	1009

7590 04/25/2007  
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EXAMINER
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HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/25/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/626,246	ELLIOTT, CHRISTOPHER J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5-24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 13-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-12,24 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Drawings*

1. The drawings were received on 02/05/07. These drawings are accepted.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1, 2, 5-11, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki (USPN 5, 980, 514) in view of Villar (USPN 6,287,318).**
4. Kupiecki discloses an embolic coil comprising an elongated core element (Fig 8, 204) formed of a shape memory material, nitinol, (Col 14, line 16) treated to define a memorized secondary coil shape; and an elongated outer element (202) wound around the elongated core element to define a primary coil shape of the embolic coil and formed of platinum (Col 14, line 18). It is inherent that the shape memory material, of which the elongated core element is formed, is in an austenitic phase at an operation temperature of the embolic coil. The secondary coil has a secondary coil memorized shape, wherein, when heated to a temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape (Col 14, lines 33-35).
5. Kupiecki does not disclose that the coil has fibers.

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6. Villar discloses an embolic coil comprising polymeric fibers, which promote tissue growth by facilitating the formation of scar tissue, healing tissue or neocapillaries in vascular occlusions. Villar discloses that the fibers are looped through the turns of the coils to lower the overall diameter of the device for ease of delivery (Fig. 2, Col4, lines 53-58). This meets the limitation that the fibers are gripped (by the coil that it is looped around) between adjacent coils.

7. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the fibers into the coil since they enhance the performance of the coil as stated by Villar. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

8. Regarding claim 11, Kupiecki in view of Villar discloses the invention substantially as claimed as stated above. However Kupiecki in view of Villar fails to disclose fiber retention grooves. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the embolic coil. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

9. Regarding claim 5, Kupiecki in view of Villar teaches an outer elongated element with a primary coil shape but is silent as to how the primary shape is formed. The claimed phrase "cold working" is being treated as a Product by Process limitation that is the primary shape of the outer elongated element is formed by cold working. As set

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forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

10. Thus, even though Kupiecki is silent to the process used to form the cut, it appears that the product disclosed by Kupiecki would be the same or similar as that claimed; especially since both applicant's product and the prior art product has an embolic coil with a core and an outer element and a primary and secondary shape.

**ALTERNATIVELY:**

**11. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki in view of Ferrera (USPN 6,171,326).**

12. Kupiecki discloses all the limitations of the instant invention substantially as claimed as stated above except for applying cold work to the outer element and the elongated outer element comprising a platinum wire co-wound with a shape memory material.

13. Ferrera discloses an embolic coil that incorporates the use of a multi-stranded micro-cable comprising both shape memory strands and radiopaque strands that can be platinum (Figs. 5 and 6 and Col 6, line 47 – Col 7, line 42). The advantage of using a multi-stranded cable is the relative flexibility and resistance to kinking compared to a single wire resulting in less trauma to surrounding tissue and ease of placement in small body cavities.

14. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of the multi-stranded micro cable into the embolic coil to result in a device where the elongated outer element comprises a platinum wire co-wound with a shape memory material wire. Ferrera provides the motivation stating that the multi-stranded micro-cable resists kinking and is more easily delivered without causing trauma to the tissue. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

15. Ferrera teaches cold working as a way of shaping embolic coils (Col 3, line 63-64).

16. As an alternative to the product by process rejection stated above, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of cold working since it is a known process in the art as disclosed by Ferrera. The inventions are analogous with each other and the instant invention and therefore the combination is proper. Therefore, even if “cold working” results in different structural characteristics of the end product than other methods, it still would have been *prima facie* obvious at the time the invention was made to use “cold working” in Kupiecki

as claimed since Ferrera teaches that "cold working" is recognized as a useful technique for forming embolic coil shapes.

### ***Response to Arguments***

17. Applicant's arguments filed 02/05/07 have been fully considered but they are not persuasive. Applicant states that Villar does not provide the missing limitation "a plurality of fibers gripped between adjacent coils of the primary coil" when combined with Kupiecki. Examiner respectfully disagrees. The term gripped does not require that the fibers are held in place by friction as stated in the specification or that the fibers are "held in place by contact between the adjacent coils" as applicant states in the remarks (page 11, line 9). The term grip is defined to mean "*A manner of grasping and holding*" according to *The American Heritage® Dictionary of the English Language, Fourth Edition*.

Examiner asserts that the coil in Fig. 2 is gripping the fiber at the intermediate locations (as opposed to the end locations). If the coils were not gripping the fiber at the intermediate locations, the length of the fiber between the two attached ends would be free to move around and extend annularly creating an overall larger diameter. Villar specifically shows the fibers being gripped by the coil to avoid this problem. The claims do not specifically require that the fibers are gripped by friction fit between adjacent coils or that they are held in place by contact with adjacent coils.

### ***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh 

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER  
